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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,058	04/10/2002	Florian Kern	100725-/Kreiser 1099-KGB	9559
27384	7590	03/03/2005	EXAMINER	
NORRIS, MCLAUGHLIN & MARCUS, PA 875 THIRD STREET 18TH FLOOR NEW YORK, NY 10022			MOSHER, MARY	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 03/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/980,058

Applicant(s)

KERN ET AL.

Examiner

Mary E. Mosher, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,7-9 and 12-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,7-9 and 12-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date: 3/2/05
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

Claims 1, 2, 12, 13, 14, and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a "new matter" rejection. Applicant is requested to point to support for the new limitations " R_N represents... a substituted or unsubstituted amino group" and " R_C represents.... a carboxyl or an ester or amide thereof" as support for these new limitations is not apparent to the examiner.

Claims 1, 2, 7-9, 12-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 uses improper Markush language in reciting "the group consisting of....or..."

The claims are also confusing in that claim 1 uses the term "peptide" broadly in the preamble and more narrowly as "peptides" in (a) as distinct from "derivatives" in (b); claim 1 is also confusing in how it is organized. The claim recites (a) peptides (with N and C-terminal R groups); (b) derivatives; then backtracks to recite the definition for the R groups of the (a) peptides, then jumps back to part (b) to define the derivatives as substitution variants. This muddles whether products with the specified R's are part of the "peptides" subgroup or part of the "variants" subgroup.

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Then dependent claims refer to "peptides or peptide derivatives of claim 1", which is confusing as it is not clear whether everything in claim 1 is "peptides" as stated in the preamble, or only the (a) subgroup is "peptides". See "Allowable subject matter" below for suggested claim language to more clearly define the invention.

Claims 12 and 13 are still incomplete, as the added steps of "comparing the production of T cells..." and "comparing the number of induced T cells..." still does not correlate the results of the assay to the determination of the response recited in the preamble. See "Allowable subject matter" below for suggested claim language which includes language correlating the "detecting" step to the response discussed in the preamble.

Claim Objections

Claim 2 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The peptides of claim 2 are different from SEQ ID NO:2 by deletions, not by substitution of 1-3 amino acids. Therefore they are outside the scope of the claim 1 subject matter.

Allowable Subject Matter

The following claims are suggested as allowable replacements for claims 1, 2, 7-9, 12-16.

17. (New) An isolated and purified peptide selected from the group consisting of:

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R_N - Ala Arg Ala Lys Lys Asp Glu Leu Arg Arg Lys Met Met Tyr Met- R_C (SEQ ID No.2),

R_N - Asp Glu Leu Arg Arg Lys Met Met Tyr Met- R_C (SEQ ID No. 3),

R_N - Glu Leu Arg Arg Lys Met Met Tyr Met- R_C (SEQ ID No. 9),

R_N - Asp Glu Leu Arg Arg Lys Met Met Tyr - R_C (SEQ ID No. 10),

R_N - Asp Glu Leu Arg Arg Lys Met Met Tyr Met - R_C (SEQ ID No. 14), and

derivatives of R_N - Ala Arg Ala Lys Lys Asp Glu Leu Arg Arg Lys Met Met Tyr

Met- R_C (SEQ ID No.2) having a substitution of one, two or three amino acids;

wherein R_N represents -H or an amino protective group, R_C represents -OH or a carboxy protective group, and said peptide has the ability to induce the production of interferon- γ or TNF- α in CD8+ T cells.

18. (New) The peptide according to claim 17 having the sequence

R_N- Ala Arg Ala Lys Lys Asp Glu Leu Arg Arg Lys Met Met Tyr Met R_C (SEQ ID No.2),

R_N - Asp Glu Leu Arg Arg Lys Met Met Tyr Met- R_C (SEQ ID No. 3),

R_N - Glu Leu Arg Arg Lys Met Met Tyr Met- R_C (SEQ ID No. 9),

R_N - Asp Glu Leu Arg Arg Lys Met Met Tyr - R_C (SEQ ID No. 10), or

R_N - Asp Glu Leu Arg Arg Lys Met Met Tyr Met - R_C (SEQ ID No. 14).

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19. (New) The peptide according to claim 17 wherein R_N represents -H or an acyl group and R_C represents -OH or an amino group.

20. (New) The peptide according to claim 19, wherein R_N represents -H and R_C represents -OH.

21. (New) Method for identifying a cellular immune system response against HCMV, said method comprising:

- a) incubating T-cells with a peptide according to claim 17; and
- b) detecting whether incubation has resulted in the production of interferon- γ or TNF- α in CD8+ T cells,

wherein production of interferon- γ or TNF- α in the CD8+ T cells identifies a cellular immune system response against HCMV.

22. (New) Method for quantifying a response of the cellular immune system against HCMV, said method comprising:

- a) incubating T-cells with a peptide according to claim 17; and
- b) detecting the number of CD8+ T cells that have been induced to produce interferon- γ or TNF- α ,

wherein the number of induced CD8+ T cells quantifies a cellular immune system response against HCMV.

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23. (New) An isolated or purified DNA which codes for a peptide according to claim 17.

24. (New) A plasmid or vector comprising a DNA according to claim 23.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on M-T and alternate F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

3/2/05


MARY E. MOSHER
PRIMARY EXAMINER
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